UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,630	09/21/2001	Peter Knox	PA 9847	5704

36335 7590 08/25/2005

AMERSHAM HEALTH
IP DEPARTMENT
101 CARNEGIE CENTER
PRINCETON, NJ 08540-6231

EXAMINER	
LAM, ANN Y	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,630	KNOX ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S8

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duke-Cohan et al., 6,265,551, in view of Balamore, WO 95/27438.

Duke-Cohan et al. disclose the invention substantially as claimed.

More specifically, as to claims 1 and 10, Duke-Cohan et al. discloses an in vitro method which is a test involving a reaction of one or more biological molecules (col. 4, lines 11-18, and col. 3, lines 45-56) and which comprises:

labeling a biological molecule (col. 3, lines 53-54), wherein one of said one or more biological molecules comprises an assay reagent (col. 3, line 50-54);

conducting said reaction (col. 3, lines 45-46); and

observing a magnetic response resonance spectrum and/or NMR image of the label during the course of said reaction (col. 3, lines 65-66).

As to claims 3 and 4, the assay is an immunoassay or binding assay (col. 3, lines 45-46 and 50-54.)

As to claim 5, the molecule is a peptide or a protein (col. 1, lines 25-26.)

Although Duke-Cohan et al. teaches use of a radioactive label as a detectable substance (col. 3, lines 53-54 and lines 64-65), Duke-Cohan et al. however does not explicitly disclose that the label used in the NMR spectroscopy is hyperpolarized ^{129}Xe.

Balamore discloses an in vitro method (see page 7, lines 20-21 and page 9, lines 26-30) comprising labeling a biological molecule with hyperpolarized ^{129}Xe (see page 6, lines 12-20), and observing a change with time of a magnetic resonance spectrum (NMR) and/or NMR image of the hyperpolarized xenon in the environment of the biological molecule during the course of said reaction (see page 7, lines 6-12.)

It would have been obvious to one of ordinary skill in the art to utilize hyperpolarized ^{129}Xe taught by Balamore as the detectable NMR label generally disclosed in the Duke-Cohan et al. method because Balamore teaches that it provides the advantage as a detectable label in an in vitro biological system, such as the Duke-Cohan et al. in vitro biological assay system.

And as to claims 6-9, Duke-Cohan et al. also does not disclose that the hyperpolarized ^{129}Xe is enriched at a level of 40% or more, or that the degree of hyperpolarisation is 8% or more, or that the method is performed in a solution wherein the solvent has a viscosity in the range of 700 to 1500 mPs, or that the pressure of the xenon gas is at least 5 bar.

Since these conditions are generally disclosed in Balamore and these claimed ranges appear to be the optimum or workable ranges, it would have been obvious to modify the Duke-Cohan et al. reference to provide these ranges because it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum of workable ranges involves only routine skill in the art (In re Aller, 105 USPQ 233.)

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are not persuasive.

Applicant argues that Duke-Cohan et al. teaches that examples of detectable substances include metal ions detectable by nuclear magnetic resonance (col. 3, lines 65-66) but there is no suggestion that an NMR-detectable label could be anything other than a metal ion and certainly no suggestion that it could be a hyperpolarized noble gas.

In response, the Office notes that Duke-Cohan et al. does suggest that an NMR-detectable label could be something other than a metal ion because Duke-Cohan et al. teaches that a detectable substance could for example be a radioactive label (col. 3, lines 53-54) and also lists as an example of a detectable substance radioactive metal ions detectable by nuclear magnetic resonance (col. 3, lines 63-66.) Duke-Cohan et al. in other words does not limit the type of detectable substance nor the type of radioactive label to only metal ions, but rather only lists radioactive metal ions as an example.

Applicant also argues that Balamore does not relate to an assay method which is an *in vitro* test involving a reaction of one or more biological molecules. Applicant argues that Balamore relates to a method of taking static images of a biological system, and that the imaging of biological systems an the monitoring of the reaction of biological molecules are not in the same field of art.

In response, the Office points out that Balamore teaches that the noble gas being imaged may include an *in vitro* chemical or *in vitro* biological system (see page 7, lines 20-22.) Thus, the teachings of Balamore and Duke-Cohan are in the same field of art at least in part because they both relate to imaging of *in vitro* analysis.

Applicant also argues that there is no reason why one of skill in the art of assay methods such as those taught by Duke-Cohan et al. would consider using an imaging agent as taught by Balamore as a detectable label. In response, the Office reasserts that Balamore provides the motivation to utilize hyperpolarized ^{129}Xe for the magnetic resonance imaging in the Duke-Cohan et al. method because Balamore teaches that it provides the advantage as a detectable label for magnetic resonance imaging in an in vitro biological system, such as the Duke-Cohan et al. in vitro biological assay system.

Applicant further argues that claim 10 additionally requires observing a change with time of the ^{129}Xe NMR spectrum and that there is no specific disclosure in Duke-Cohan et al. of the monitoring of a reaction over a period of time. This is not persuasive because, as indicated above, Balamore et al. disclose monitoring of a reaction over a period of time (see page 7, lines 6-12.) (The Office notes that Duke-Cohan et al. also teaches monitoring of a reaction over a period of time, see for example, column 13, lines 44-47.)

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
08/22/05